REMARKS

Claims 12-22 are pending. No amendments to the claims are made. The specification is amended to insert the phrase "Brief Description of the Figure" as suggested by the Examiner.

Obviousness-type Double Patenting

Claims 12-22 are provisionally rejected as unpatentable over claims 1-19 of co-pending application 10/492,320. Since the rejection is provisional and US 10/492,320 is awaiting examination, Applicants respectfully request that the rejection be held in abeyance pending the determination of patentable subject matter. Applicants suggest that if all other rejections are overcome, it is appropriate to withdraw the provisional double-patenting rejection and allow the instant application to issue, and apply any double-patenting rejections deemed necessary by the Examiner to the later application, as directed by the MPEP:

> If the "provisional" double patenting rejection is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. (MPEP 804.1B)

35 U.S.C. § 112, first paragraph

Claims 12-22 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Office Action states that "[o]nly through experimentation are optimal regimens determined" (Office Action, page 5). However, the Office Action concedes that "[t]he instant specification is enabling for some cancer therapy," (Office Action, paragraph bridging pages 5-6). Applicants respectfully traverse the rejection.

Applicants request withdrawal of the rejection of claim 18 in view of the statement in the Office Action that the specification provides support for the treatment of various specific cancers and that the instant specification is enabling for some cancer therapy. Specifically, the Office Action concedes that "[t]he specification provides support for the treatment of melanoma, leiomyosarcoma, colon stromal sarcoma, gastric stromal sarcoma, osteosarcoma, liposarcoma, breast cancer, ovarian cancer, mesothelioma, ocular melanoma," (Office Action, apge 3). The arguments in the Office Action regarding "breadth" and the other *Wands* factors are moot in view of the specific listing of 10 different forms of cancer in claim 18.

With respect to the remaining claims, the Office Action applies an improper standard where "[o]nly through experimentation are optimal regimens determined" (Office Action, page 5). The patent statutues do not require that claims to therapeutic regimens be limited to optimized regimens. Applicants are not required to claim only optimal regimens, and the claims should not be interpreted as being limited to optimized regimens. Rather, the instant claims encompass a range of treatment options. One of ordinary skill in the art is clearly taught to use the invention by administering Et 743 in cycles by intravenous infusion at intervals of about 1-6 weeks with an infusion time of about 2 to about 24 hours (as in claim 1). One of ordinary skill in the art is enabled to practice the invention by simply administering Et 743 according to the invention.

Further, Applicants traverse the requirement to only claim optimized treatments in this application because such a standard is not routinely applied to other applications. A cursory review of US patents shows 738 patents with claims to a "method of treating cancer," such as US 6,153,590. In the case of US 6,153,590 (examined by Christopher Low), the claims were allowed where the specification contains no disclosure of results in human, but rather relies on data from

cell lines. There is no basis for the Examiner to apply an improperly higher standard to the present application which has *in vivo* human data than that which has been applied by the Patent Office to other applications with less data.

Applicants bring the Examiner's attention to US 5,552,544 to Brana et al. The application that ultimately issued as US 5,552,544 was rejected during the course of prosecution under 35 USC § 112, first paragraph, for lack of enablement. In reversing the rejection during an appeal, the Federal Circuit stated

> The Commissioner, as did the Board, confuses the requirements under the law for obtaining a patent with the requirements for obtaining governmental approval to market a particular drug for human consumption. ***See Scott v. Finney**, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994)* ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.").

In re Brana, 51 F.3d 1560, 1567 (Fed. Cir. 1995). Nevertheless, Applicants have provided the USPTO in the instant application with numerous examples of results in humans from clinical trials. Again, in *Brana*, the Federal Circuit stated

> Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.
> **In veiw of all the foregoing, we conclude that applicants' disclosure complies with the requirements of 35 U.S.C. § 112 P1.** [emphasis added]

In re Brana, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

Applicants have gone well beyond the requirements for patentability as indicated by the Federal Circuit by providing data in human clinical trials. Applicants provide detailed examples for the administration of Et-743, including dosing regimens in humans and methods of evaluating the results of human clinical trials. See Figure 1, which includes data from a variety of patients in clinical trials in humans. Example 1 shows that 6 out of 10 cancer patients exhibited stable disease or minor responses after 2 cycles of therapy. Example 2 shows that six human patients achieved disease stabilization following treatment. Example 3 shows that in 18 of 34 evaluable patients, a partial response, minor response, or disease stabilization in humans was achieved. Therefore, numerous working examples for the treatment of a variety of cancers are provided in the specification.

With respect to predictability, the Office Action has unfairly ignored the actual data from human clinical trials presented in the Examples. According to the MPEP, "as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility," (MPEP 2107.3: IV).

Examples 1-3 prove that Et 743 can be used in a method of treatment of a human patient for cancer, comprising administering Et 743 in cycles by intravenous infusion at intervals of about 1-6 weeks with an infusion time of about 2 to about 24 hours. The Examiner's desire for optimized regimens notwithstanding, one of ordinary skill in the art would have a reasonable expectation of success based on the instant application, and therefore undue experimentation is not required to practice the invention.

Finally, Applicants traverse the Examiner's statement that the "broad recitation "treatment of a human patient for cancer" is inclusive of many pathologies that presently have no

established successful therapies," (Office Action, page 5). If the Examiner is taking the position of "official notice", Applicants request that the Examiner provide documentation of a cancer for which no treatment is provided. Applicants are unaware of any type of cancer that is 100% fatal and absolutely unaffected by any and all treatment as suggested by the Examiner.

Withdrawal of all prior art rejections

Applicants acknowledge the withdrawal of all prior art rejections.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application. In the event that an enablement rejection is maintained, Applicants request clarification as to allowable subject matter in view of the Examiner's statement that "[t]he instant specification is enabling for some cancer therapy," (Office Action, paragraph bridging pages 5-6).

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 4126-4007.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for

an extension of time to Deposit Account No. 13-4500, Order No. 4126-4007. A DUPLICATE OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: August 30, 2005 By: _____

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